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10/698,160	10/30/2003	De Chao Yu	CELL-023	9850

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EXAMINER

GUZO, DAVID

ART UNIT PAPER NUMBER

1636

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/698,160

Applicant(s)

YU ET AL.

Examiner

David Guzo

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,8-10 and 17-20 is/are allowed.
- 6) ☒ Claim(s) 2,4-6 and 12-16 is/are rejected.
- 7) ☒ Claim(s) 3 and 7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 2 and 6 are rejected under 35 U.S.C. 102(a) as being anticipated by Chia et al.

Applicants claim an adenovirus vector according to Claim 1, wherein said EBV-specific TRE comprises a sequence 5' to the translational start codon for the LMP1 EBV gene (SEQ ID NO:1) or an adenovirus vector according to Claim 1, wherein said EBV-specific TRE comprises a sequence 5' to the translational start codon for the LMP2A EBV gene (SEQ ID NO:2). Claim 1 recites a replication-competent adenovirus vector, comprising a first adenovirus gene essential for replication under transcriptional control of an Epstein Barr Virus (EBV)-specific transcriptional regulatory element (TRE) comprising a sequence selected from the group consisting of a sequence upstream of the translational start codon for the LMP1 gene presented as SEQ ID NO: 1, a sequence upstream of the translational start codon for the LMP2A gene presented as SEQ ID NO:2 and the Cp promoter sequence presented as SEQ ID NO:3. Claims 2 and 6 are broader than claim 1 in that they recite that the EBV-specific TRE comprises a sequence 5' to the translational start codon for the LMP1 EBV gene (SEQ ID NO:1) or a sequence 5' to the translational start codon for the LMP2A EBV gene (SEQ ID NO:2). Claim 2 and 6 therefore read on any EBV TRE comprising any sequence (i.e.

Art Unit: 1636

two or more contiguous nucleotides) of SEQ ID NO:1 or 2. This also explains why dependent claims 2 and 6 are rejected under 35 USC 102(a) while the claim from which they depend is not.

Chia et al. (cited in previous Office Action) recite a replication- competent (conditionally replication competent) adenovirus vector comprising a Epstein Barr virus (EBV) specific TRE (ori-FP) comprising FR enhancer sequences and a CMV minimal promoter operably linked to a adenoviral coding region (minus it's endogenous promoter) essential for replication (E1a). The ori-FP EBV sequence comprises a sequence (i.e. GC or CT, etc.) from SEQ ID NO:1 or 2. Chia et al. therefore teaches the claimed invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2 and 6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' invention is as described above. Applicants define a "EBV specific transcriptional response element" as an element that "preferentially directs gene expression in EBV-associated cancer cells". The term is construed to read on any

Art Unit: 1636

transcriptional response element (i.e. an EBV element or a cellular TRE or another viral element, etc.) that is preferentially active in EBV associated cancer cells. Claim 2 and 6 read on any EBV TRE comprising any sequence (i.e. two or more contiguous nucleotides) of SEQ ID NO:1 or 2. The claims therefore read on a genus of EBV specific transcriptional response elements (from any source) in the adenoviral vectors. Applicants provide a written description for EBV TREs which are EBV specific transcriptional response elements.

The written description requirement for a genus may be satisfied by sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that applicant was in possession of the claimed invention. In the instant case applicants only disclose EBV TREs which preferentially direct gene expression in EBV-associated cancer cells. Applicants disclose no non-EBV TREs which preferentially direct gene expression in EBV-associated cancer cells. Applicants present no disclosure of the relevant identifying characteristics of non-EBV TREs, i.e. applicants do not disclose how the sequences in the EBV TREs relate to non-EBV sequences (no structure-function analysis is presented) which would have the same properties of preferentially directing gene expression in EBV-associated cancers. Given applicants disclosure, the skilled artisan would be unable to envision the non-

Art Unit: 1636

EBV members of the claimed genus and said artisan would conclude that applicants were not in possession of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 4-6, 12-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 and 6 are vague in the recitation of the phrases "LMP1 EBV gene (SEQ ID NO:1)" and "LMP2A EBV gene (SEQ ID NO:2)". The claims refer to a broad limitation (i.e. a sequence 5' to the translational start sites of any LMP1 gene or LMP2A gene) followed by a narrow limitation (SEQ ID NO:1 or 2). It is unclear if the EBV TRE sequences recited in the claims are from the regions 5' to the translational start sites of any LMP1 gene or LMP2A gene or refer to the specific SEQ ID NO:s.

Claims 4 and 5 are vague in that it is unclear what portions of SEQ ID NO:1 comprise the "ED-L1" and "L1-TR" regulatory regions. Without an indication of the boundaries of these two promoters within the 5' region of the LMP1 gene, the metes and bounds of the claimed sequences are unclear.

Claim 12 (and dependent claim 13) are vague in the recitation of "a second adenoviral geness (emphasis added)". Possibly applicants mean to recite "a second adenoviral gene".

Claim 14 is vague in that there is no antecedent basis for the term "said adenoviral gene". Claim 1 recites a "first" adenoviral gene essential for replication and it is unclear what adenoviral gene is being referred to in claim 14.

Claims 2 and 6 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 2 and 6 are broader than the claim from which they depend (claim 1) because the claims recite "a sequence" 5' to the translational start codon for the LMP1 EBV gene or SEQ ID NO:1 or the LMP2A gene or SEQ ID NO:2 while claim 1 recites the specific sequences of SEQ ID NO:1 or 2. Claims 2 and 6 recite a EBV TRE comprising any sequence of SEQ ID NO:1 or 2 or any sequence of a sequence 5' to the translational start sites of any LMP1 gene or LMP2A gene.

It is noted that applicants' amendment to the specification filed 9/28/06 incorrectly lists the paragraph numbers for the paragraphs to be amended as [0022] and [0023]. The correct paragraph numbers are [0020] and [0021].

In view of the new grounds of rejection, applicants' arguments directed to the previous rejections, now withdrawn, are moot.

Any rejection not repeated in this Office Action is withdrawn.

Art Unit: 1636

Claims 1, 8-10 and 17-20 are allowed.

Claims 3 and 7 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo
November 30, 2006


DAVID GUZO
PRIMARY EXAMINER